Morbidity analysis of Modalities of temporary faecal diversion following operations for Colo-Rectal cancers.

A thesis dissertation submitted to the Dr.M.G.R. Medical University, Tamilnadu, in partial fulfillment of the requirements for M.S. Branch-1 (General Surgery) examination to be held in Jan 07.

Certificate

This is to certify that the dissertation titled "**Morbidity analysis of modalities of faecal diversion following operations for colo-rectal cance**r" is a bonafide work done by Dr. Renol Mathew Koshy in the department of General Surgery Unit V of the Christian Medical College and Hospital, Vellore, during the period of his post-graduate study for M.S.Branch I (General Surgery) from March 2004 – March 07.

Dr. Benjamin Perakath

Professor and head of General Surgery Unit V

(Colo-Rectal Surgery)

C.M.C & H, Vellore

Dr. Sitaram V.

Professor and head of General Surgery

C.M.C & H, Vellore

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God, for strength and courage to go through this exercise

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My patients, who by their graciousness gave me this wonderful opportunity to be involved with their lives and learn.

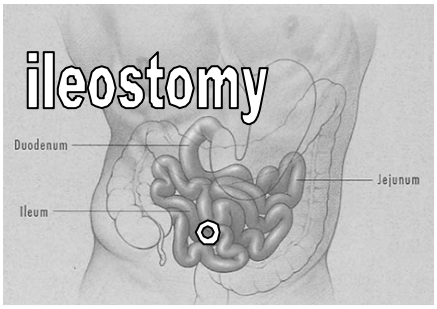
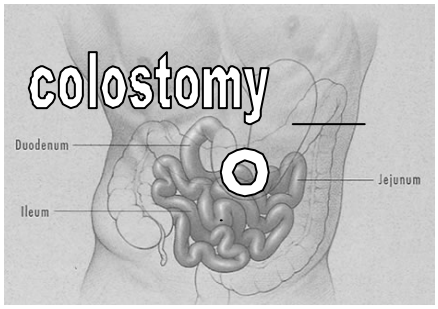
Contents

Introduction

The role of faecal diversion in colorectal surgery is hotly debated with many a studies, done many a ways to finally have no clear-cut consensus. There seems to be a consensus however, to differ based on experiences and prejudices. The western literature has a clear line drawn between surgeons who prefer either one of these modalities. To add to the complexity of the situation, there is also another group of surgeons who question the very role of a diversion stoma. In this interesting mayhem, it is important for us to have our own conclusions based on our experiences in the light of our cultural, social and dietary differences amongst the many others.

This study is to look at the morbidity pattern amongst our ostomates and to corroborate it to their quality of life. We hope that this can influence our clinical practice.

From the data available comparing stomas, the following are the **general characteristics**

Characteristics	**Ileostomy**	**Colostomy**
Site	Ileum-Small intestine 	Transverse.Colon-Large intestine 
Nature of contents	Large volume, watery, non-offensive odour, irritates skin.	Smaller volume, semi-solid, offensive odour, not as irritative.
Problems	Intestinal obstruction Retraction Stenosis Necrosis Skin breakdown & wound infection Prolapse Stomal bleeding Parastomal hernia	Intestinal obstruction Retraction Stenosis Necrosis Skin breakdown & wound infection Prolapse Stomal bleeding Parastomal hernia

The Evolution of Stoma

- Hippocrates 460-377 BC & Celsus 53-7 AD recorded that the wounds of the large intestine were not deadly as compared to small intestine and bladder
- 1776 first planned colostomy by M. Pilone
- 1793 first successful left Inguinal colostomy by Duret
- 1797 first transverse colostomy by Prof. Fine
- 1820 documentation and identification of stoma related complications and ostomy appliances by Daniel Pring
- 1716-1839 retrospective review of 27 cases done ever, only 6 had survived – Amussat
- 1879 first recorded ileostomy by Baum
- 1883 a successful recovery recorded by Maydi
- A flush loop stoma described at the JHH by Finney
- 1952 everted modification of the ileostomy described by Prof. Bryan Brooke
- 1972 continent ileostomy described by Nils Kock
- 1971 ilial reservoir / pouch described by Peck.

Review of literature

The need for diversion

Anastomotic leak has been the major concern in operations for low rectal cancers (1). Proximal diversion, either by a colostomy or an ileostomy, by allowing decompression of the anastomosis, minimizes the consequence of the anastomotic dehiscence (2). The use of a stoma, however, did not protect against developing an anastomotic leak (2). In a meta-analysis to look at the quality of life after rectal resection for cancer, there was no apparent difference in the quality of life in patients with stoma when compared to the no-stoma group (3).

The comparison

A transverse loop colostomy was the conventional method to defunction left sided and rectal anastomoses. It is relatively safe and easy to construct, but is associated with several disadvantages. Its site and bulk make the appliances difficult to fit; the effluent is of offensive odour (4).

The studies in favour of loop colostomies are by

Gooszen et al 1998 (5);(The Netherlands) in their randomized controlled study looking at patients from the construction to the closure of their stomas with respect to morbidity found transverse loop colostomies to be better for decompression of the left colon.

Law et al 2002 (6) ;(Hong Kong) in their randomized controlled study comparing the stoma-related morbidities found the incidence of intestinal obstruction and ileus less common after loop colostomies.

Gohring 1988 (7) and Gastinger 2005 (8); in their randomized controlled studies to look at morbidities associated with stoma closure found ileostomies to be technically more complicated and have more complications when as compared to colostomies.

In view of the problems faced by the colostomies, loop ileostomies were propagated.

The studies in favour of loop ileostomies are by

Edwards et al 2001 (9); in their randomized controlled study comparing the stomas found ileostomies, easier to manage.

Khoury et al 1987 (10); in their randomized controlled study found the colostomies to be associated with a greater incidence of anastomotic breakdown and ileus.

Williams et al 1986 (11); (UK) in their landmark prospective controlled study looking at somas from creation to closure, found ileosotmies more suitable, as they were associated with less odour, fewer appliance changes, and lesser incidence of wound infection at closure.

Torkington et al 1998 (12); in their randomized controlled study comparing morbidities amongst stomas found the larger group of patients comfortable with an ileostomy.

Rullier et al 2001 (13); (France) in their randomized controlled study in patients under going rectal cancer surgeries found that the overall stoma-related morbidity and risk of re-operations were lower with loop ileostomies.

Fasth et al 1980 (14); in their trial looking at the safety of the methods, found loop ileostomies more reliable for defunctioning. It also appeared that ileostomies promoted swifter convalescence with fewer stoma-related problems.

The above mentioned studies were all western, from the European and American continents. The search to find any regional variation as we would expect,

considering the cultural and social differences brought a few studies from the south-east Asian and the Indian sub-continent into the picture
Chen et al 1996 (15); from Hong Kong, in their study found loop ileostomies to be a better modality of diversion, as patients found them easier to manage. Silva et al 2003 (16); from Sri Lanka in their study to look at Quality of life amongst the ostomates, also found the loop ileostomy to be a more tolerable stoma type.

These evidences presented, make it evident that both the stomas had their own supporters for obvious reasons. However, there seems to be a lop-sided support to ileostomies considering the numbers. This subjective feeling is negated by the meta-analysises that add the objective angle to the debate. Both the modalities of diversion demand respect for their unique features. The decision on the type of stoma to be used had to circumstantial, tailored to the needs of the individual. Gooszen et al 2000 (17) from the Netherlands, conducted a prospective trial where by they looked at the impact of complications and stoma-related problems on the daily life of patients with a temporary stoma. They found that there was no relation between stoma type and social restriction. However, social restriction was directly related to problems with stoma care. Also, Sakai et al 2001 (18) in their case matched study found the choice of stoma to be equivalent with regards to safety.

Conclusions?

The lack of consensus in literature makes it obvious that both the modalities deserve respect for their own unique features. The divide seems to be well placed in that, that there were well established schools of clinical practice based on their experiences.

The ileostomy did well, when the management of the stoma was concerned with the added advantage of being odourless. The ileostomies moved earlier, and resulted in faster recovery. The ileostomies were also simple to create and close. The peristomal excoriations made ileostomy unpopular. The incidence of electrolyte imbalances was more with the ileostomies. The other drawback was the higher incidence of intestinal obstruction amongst these ostomates.

The colostomy seems to have captured the fancy of the surgeon traditionally. The bulk and the appliance related problems have seriously questioned the user friendliness of the modality. The intermittent wash outs made the continuous wearing of the appliance optional. This has given flexibility and freedom to the ostomates. The electrolyte imbalances are minimized and the physiology preserved.

The imperative needs of diversion and decompression seem to be well addressed to by both stomas, with neither significantly outdoing the other. There was a clear relation between the number of stoma care related problems and the degree of social restriction. Thus, not only a careful surgical technique, but also a good choice of stoma type has been advocated for a healthy stoma life (14).

When patients are followed from construction to closure, the conclusion is that both types of stoma carry a high complication rate with a considerable associated mortality rate (7)

The debate continues

With the literature being predominantly western, the lack of a recorded Indian experience makes the study an imperative exercise.

THE STUDY –

AIM:

To compare the morbidity associated with loop ileostomies and loop colostomies in adult patients who have undergone curative surgery for colorectal cancers.

OBJECTIVES:

1. To compare the morbidity associated with loop ileostomies and loop colostomies in adult patients who have undergone curative surgery for colorectal cancers
2. To compare the effect of loop ileostomy and loop colostomy on the nutritional status of adult patients who have undergone curative surgery for colorectal cancers
3. To compare the efficacy of decompression of the distal bowel loop with loop ileostomy and loop colostomy in adult patients who have undergone curative surgery for colorectal cancers
4. To compare the quality of life index of adult patients, with loop ileostomy and loop colostomy, who have undergone curative surgery for colorectal cancers

DESIGN:

1. Retrospective study comparing the morbidity of adult patients who have undergone curative surgery for colorectal cancers.

2. Prospective randomized study comparing morbidity, quality of life, efficacy of decompression and effect on nutritional status of adult patients who have undergone curative surgery for colorectal cancers.

SUBJECTS:

INCLUSION CRITERIA:

Adult patients with colorectal cancer who are planned for elective resectional surgery with curative intent, who have a defunctioning stoma created simultaneously during the primary surgery.

EXCLUSION CRITERIA:

Patients satisfying the inclusion criteria but did not have a stoma created.

METHODOLOGY:

The study was done in two limbs. The initial retrospective study was to look at the morbidity patterns and to identify the relevant parameters important for comparison of the stoma groups.

A. RETROSPECTIVE LIMB

1. Collection of data from the Inpatient records.
2. Include patient based on criteria.
3. Record the stoma related morbidities in either group.

B. PROSPECTIVE LIMB

1. Include patient based on criteria after informed consent.
2. Randomise the patient to either group.
3. Review routine investigations.
4. Counselling by Enterostomal therapist and siting of stoma
5. Anthropometric measures taken-B.M.I.
6. Nutritional assessment-Hb., S.Albumin.
7. Pre-op Bowel preparation and prophylactic Abs.

8. The operation with stoma creation as indicated.

9. Post-op stoma function and morbidity monitor.

10. B.M.I. at discharge.

11. Out patient review to monitor stoma related morbidity.

12. Review for stoma closure at 3 months-B.M.I., Hb. S.Alb.

13. Rectal and anal pressure recordings.

14. Q.O.L.I. assessment.

15. Post – Closure morbidity assessment.

THE RETROSPECIVE LIMB

Methodology

The inpatient records of patients, as gathered from our records were gathered and the proformas (Appendix I) filled.

A total of 55 records were gathered between 1994-2005 (12 years)

The **Descriptive details** of the group are as follows

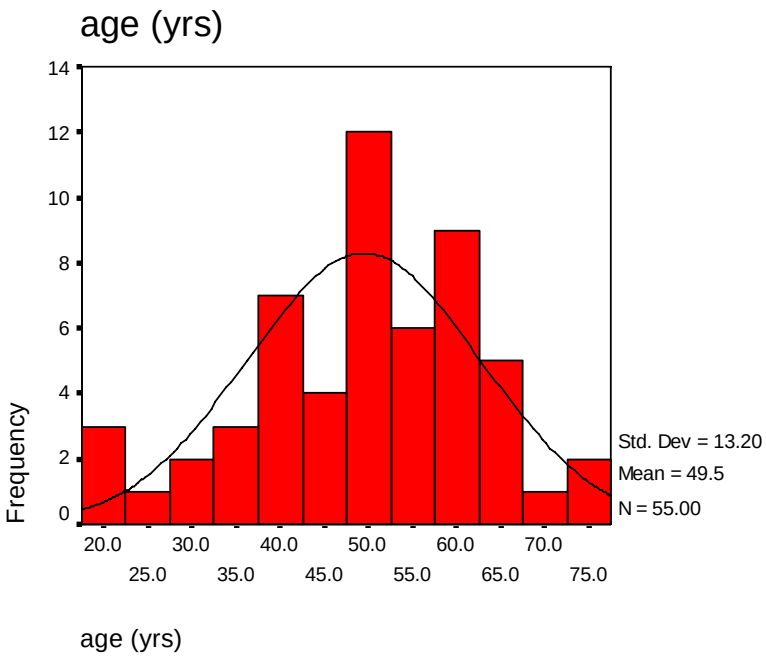
Age:

The mean age was around 50 years with the majority of the patients in the 40-60 age group.

AGE DISTRIBUTION

age (yrs)

N		55
Mean		49.49
Std. Error of Mean		1.780
Median		50.00
Mode		60
Std. Deviation		13.199
Range		56
Minimum		19
Maximum		75
Percentiles	12.5	35.00
	25	40.00
	50	50.00
	75	60.00
	87.5	63.00

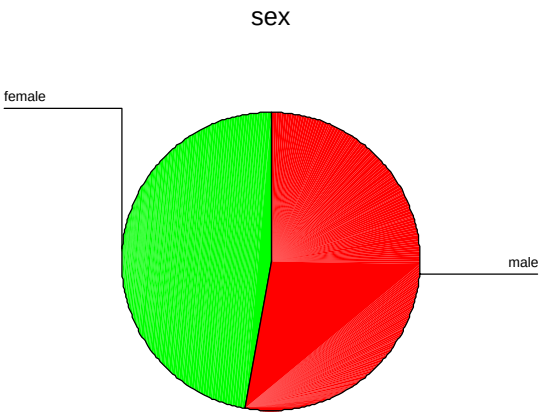


Sex:

In the study population the distribution by sex seemed insignificant with no real difference between the groups.

Distribution amongst the sexes

		Frequency	Percent	Valid Percent
Valid	male	29	52.7	52.7
	female	26	47.3	47.3
	Total	55	100.0	100.0



Stoma type:

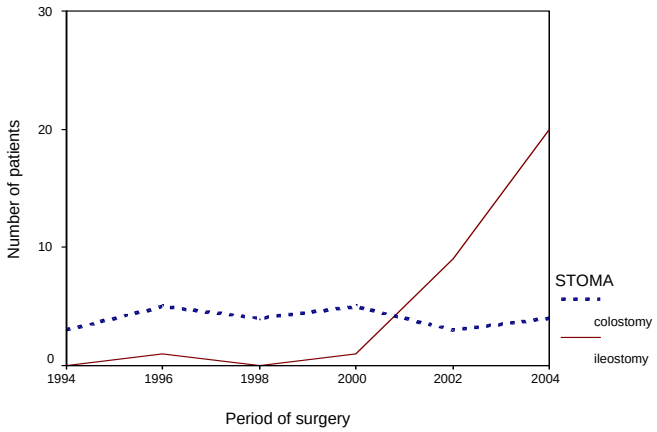
The study population had a fair number of both the groups. However there was an interesting shift of the stoma type from colostomy to ileostomy over the last decade.

stoma

		Frequency	Percent	Valid Percent
Valid	colostomy	24	43.6	43.6
	ileostomy	31	56.4	56.4
	Total	55	100.0	100.0

STOMA OVER THE YEARS – AN INTERESTING TREND?

There has been an interesting shift of stoma creation from colostomies to ileostomies, especially so since the new millennium. The reasons could be that there was a change in clinical practice over the decade as a newer breed of surgeons took over the reigns of the department.



Hospital stay:

Characteristic	Study population	Ileostomy	Colostomy	P value
M:F	29:26	15:16	14:10	NS
Age	49.49±3.6	48.5±5.2	50.7±4.7	NS
Hospital Stay (mean days)	22.65±4.4	20.1±4.9	25.9±7.6	NS
Post-op Stay (mean days)	17.55±4.25	16.0±4.9	19.0±7.5	NS

The average post-operative stay was 17.5 days with the ileostomies having a shorter stay than the colostomies, though not statistically significant.

The Average age amongst the two groups was around 50 years and did not seem to have a bearing on the length of hospital stay.

There were no biases amongst the sexes to the stoma type, and this too had no relation to the hospital stay.

Stoma-related Morbidity

A significant number of patients (27/55 = 49.1 %) seem to have a morbidity or the other. Ileus was the most common of the morbidities with wound infection, the next most common problem. However, neither of the morbidities seemed to be related to the stoma type.

Eight of the patients had a re-operation and the leak rate was 14.5% with no significant difference between both the groups.

Characteristic	Study population (no. of patients) (n=55)	Ileostomy (n=31)	Colostomy (n=24)	P value
Morbidity	27	17	10	NS
Ileus	22	15	7	NS
Wound infection	7	3	4	NS
Anastomotic leak	8	5	3	NS
Re-operation	10	5	5	NS
Others	1	0	1	NS

Relationship between Co-morbidities and Stoma-related Morbidity

Characteristics	Study Population (no. of patients) (n=55)	With Morbidity (n=27)	No Morbidity (n=28)	P value
Age (mean±2S.E.) in years	49.49±3.6	49.0±5.6	49.96±4.6	NS
Sex (m:f)	29:26	14:13	15:13	NS
ASA grade 1	23	16	23	
ASA grade 2	15	10	5	NS
PCV in % (mean±2S.E.)		33.7±2	34.6±2	NS
Albumin in g% (mean±2S.E.)		4.0±0.2	4.0±0.1	NS
Pre-op Chemotherapy	2	1	1	NS
Pre-op Radiotherapy	6	2	4	NS
Bowel Preparation	36	19	17	NS
Post op. Epidural	49	25	24	NS

The comparison of morbidity to the co-morbidities did not reveal any relation between them. So, the presence of anaemia, hypoalbuminaemia, other medical illnesses (as denoted by the ASA gr.), pre-op Chemotherapy or Radiation therapy did not predispose to morbidities, as we would have inferred.

Bowel preparation seems to confer no benefit in reducing morbidity.

The use of Epidural analgesia in post-operative pain relief seems to have no statistical relationship to the incidence of ileus.

Indication for Re-operation

Indications	Study population (no. of patients) (n=55)	Ileostomy (n=31)	Colostomy (n=24)	P value
Re-operation	10	5	5	NS
Anastomotic Leak	8	5	3	NS
Stomal Retraction, Necrosis and Obstruction	0	-	-	-
Wound Infection	2	0	2	NS

Amongst the indications to reoperate, anastomotic leak was the major indication, with no relation to the type of stoma. So, if to prevent anastomotic leak was the major indication to create a stoma in the first place, it looks like the choice had no bearing to post-op sequel.

Mortality

Three out of the fifty five patients died, with the mortality rate at 5.5 %. The three patients, who died, succumbed to the intra-abdominal sepsis as a consequence of the anastomotic leak.

Discussion & Conclusions:

The retrospective exercise was to build-up a data base to identify factors that affect soma-life. These insights were to be used to build-up a prospective study with the required modifications.

The retrospective limb showed that co-morbidities did not contribute to morbidities, and that the type of stoma chosen did not matter. However the patients with ileostomies had a shorter hospital stay. This retrospective data shows no relationship between the stoma type and morbidity and hence the choice of the stoma type still remains the surgeons' choice based on his experience.

The limitation of the study seems to be the data collection, which would have missed out patients due to their unavailable records. The available data too could not be used for many other questions that we would have liked to answer.

In summary,

1. There is a shift of stoma choice from the traditional Colostomy to Ileostomy.
2. The type of stoma did not affect the anastmotic complications.
3. The stoma-related morbidity did not depend on the type of stoma.
4. The presence of co-morbidities did not predispose patients to developing stoma-related morbidities.
5. Ileostomies moved faster than Colostomies, hence accelerating convalescence.

Conclusion – retrospective limb

There was no difference in the morbidity pattern between ileostomies and colostomies.

THE PROSPECTIVE LIMB

THE PILOT STUDY AND SAMPLE SIZE CALCULATION:

For *Sample size* calculation due to paucity of availability of similar data from other studies a pilot study of 11 patients (6 months) was undertaken and the proportions derived from the study was used to calculate the sample size for the study using the formula: $\mathbf{n = (2Z^2pq)/d^2}$

Where n = sample size; Z (for a = 0.05) is 1.96;

$P = (p_1+p_2)/2$; $q = 1-p$; $d = p_1-p_2$

Morbidity	Ileostomy (n=9)	Colostomy (n=2)	Sample Size
Ileus	6 (67%)	1 (50%)	65
Wound Infection	1 (11%)	1 (50%)	11
Retraction	0 (0%)	1 (50%)	6
Anastomotic Leak	3 (33%)	1 (50%)	65
Re-operation	1 (11%)	2 (100%)	3

Since the largest number among the individual Sample sizes is 65, we plan to study 65 patients for the study.

THE PROSPECTIVE STUDY

Methodology

The prospective study was undertaken with the database of the retrospective limb.

Patients undergoing curative surgery for rectal cancers with simultaneous creation of stoma were enrolled into the study in randomized fashion conducted between June 2005 and June 2006, in the department of general surgery unit V (Colo-Rectal unit) of Christian Medical College, Vellore. The patients were consented (Appendix I) and then allocated into either group based on the randomization, done by the entero-stomal therapist as prescribed by the statistician. The randomized numbers were obtained with the help of statistics software.

A standardized method of stoma creation was followed for all patients by the surgeons.

The patients were followed-up in the immediate post-op period and assessed for stoma health and function. The requirements as per the proforma (Appendix II, III) were obtained and recorded. At discharge from the ward, the patient was followed-up in the out patient clinic and the assessment continued to their visits to the stoma clinic up to the 2^{nd} week.

The patients were advised to come back at the end of 3 months for assessment of the stoma for closure.

If the patient was found fit for stoma closure, an assessment of their stoma-life was made by using the quality of life scoring system.

The QOLIS is a self structured set of parameters, which are to be answered by the patient at stoma closure. The structure was on the guidelines of the WHO criteria and modified with insights from a few other quality of life studies. This was validated on 35 patients to fine tune the scale, for further use (Appendix IV). Also the question of weather the type of stoma had a bearing on the pressures at the site of anastomosis, was to be addressed by rectal manometry.

N = 20 PATIENTS recruited between June 05-July 06.

MALE = 13

FEMALE = 7

COLOSTOMY = 7

ILEOSTOMY = 13

Measurements:

1. Demographic and Clinical details at enrollment

2. General and stoma related Morbidity on follow up

3. Nutritional status and anthropometry on recruitment and follow up

4. Quality of life index at the time of stoma closure

5. Rectal and anal manometric studies at the time of stoma closure

The Descriptive attributes of the study are as follows

Hospital stay and post-operative stay

Characteristic	Study population	Ileostomy	Colostomy	P value
Hospital Stay (mean days)	19.7	18.5	22.0	0.586
Postoperative Stay (mean days)	16.6	15.3	19.1	0.557
Days to normal diet (mean days)	8.4 (median 5.5)	9.0	7.1	0.554
Days to Flatus (mean days)	**2.6**	**2.2**	**3.0**	**0.01**
Days to Faeces (mean days)	**4.6**	**3.6**	**6.1**	**0.002**

The hospital stay for the entire group had a median of 15 days with 19.7 mean hospital days. The post-operative stay had a median of 11 days with a mean of 16.6 hospital days. The difference between the groups was augmented by the earlier recovery of bowel movement in the ileostomy group. Patients with an ileostomy, on an average moved their bowel earlier than those with colostomy. This was statistically significant. This accelerated their recovery and promoted an earlier discharge from the hospital.

Comparison between Stoma and Morbidity

In the study a total of 13 patients had morbidities, with anastomotic leak being the commonest morbidity, which also required an operative intervention.

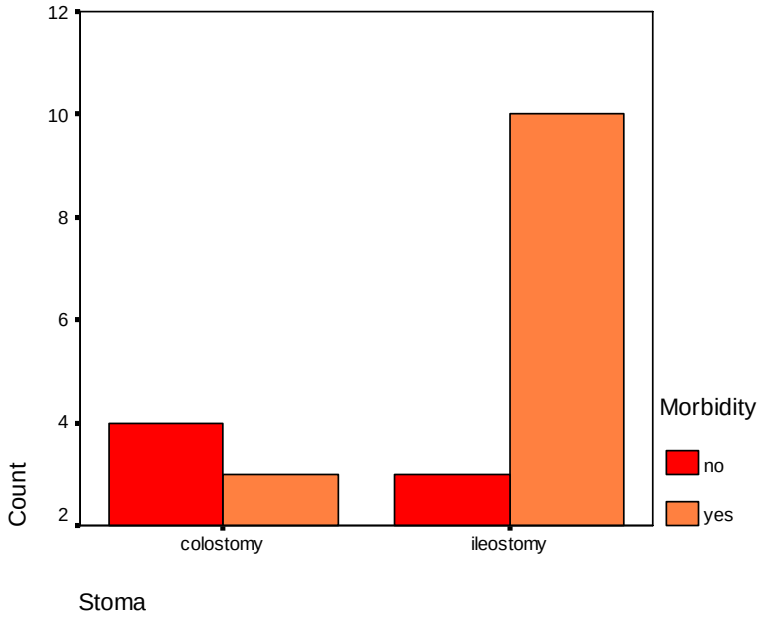
Morbidity

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	no	7	35.0	35.0	35.0
	yes	13	65.0	65.0	100.0
	Total	20	100.0	100.0	

Type of stoma in relation to morbidity

			Stoma		
			colostomy	ileostomy	Total
Morbidity	no	Count	4	3	7
		% within Morbidity	57.1%	42.9%	100.0%
			57.1%	23.1%	35.0%
		% of Total	20.0%	15.0%	35.0%
	yes	Count	3	10	13
		% within Morbidity	23.1%	76.9%	100.0%
			42.9%	76.9%	65.0%
		% of Total	15.0%	50.0%	65.0%
Total		Count	7	13	20
		% within Morbidity	35.0%	65.0%	100.0%
		% of Total	35.0%	65.0%	100.0%

Morbidity amongst the stomas



Even though, there seems to be a larger number of people with ilieostomies who had problems, it did not corroborate statistically. (p value = 0.128)

Stoma-related Morbidity

Morbidity	Study population (no. of patients) (n=20)	Ileostomy (n=13)	Colostomy (n=7)	P value
Morbidity noted in	13 (77%)	10	3	NS
Ileus	3	1	2	NS
Retraction	3	3	0	-
Wound infection	3	1	2	NS
Anastomotic leak	7	5	2	NS
Re-operation	8	6	2	NS
Others	3	2	1	NS

Out of the twenty patients recruited thirteen of them had a morbidity or other. Ileostomies seem to be more morbid with rates of 77% when compared to 43% amongst the colostomies. This observation however, could not be statistically validated.

The colostomies seemed to have a larger incidence of ileus.

Stoma retraction seemed to be noted only in the ileostomy group, all of whom required refashioning.

Wound infection was another morbidity that seemed more common in the colostomy group, probably due to the larger incidence of appliance accidents and spillage, causing contamination of the wound.

Anastomotic leak even though not a morbidity of the stoma was the commonest morbidity, with an anastomotic leak rate of 35%. Except one patient, all the others required a re-operation. However, there was no statistical difference between the groups to say that either of them provided immunity to leaks (Ileostomy – 38%, Colostomy – 28%).

Indications for Re-operation amongst the stomas

Indication	Study population (no. of patients) (n=20)	Ileostomy (n=13)	Colostomy (n=7)	P value
Re-operation	8	6	2	NS
Retraction	3	3	0	-
Anastomotic Leak	6	4	2	NS
Stoma Necrosis and Stomal Obstruction	0	-	-	-
Wound Infection	2	1	1	NS

Amongst the patients who had a re-operation, the ileostomies which retracted formed a significant indication to the second operation. Anastomotic leaks were the reason for the re-operations. All but one of the ostomates with anastomotic leaks was successfully managed in the ward.

The type of stoma had no bearing on the re-operation rates.

Relation between morbidity and co-morbidities

Characteristic	Study population (n=20)	With Morbidity (n=13)	No Morbidity (n=7)	P value
Age (mean±2S.E.) in years	46.5±5.6	46.4±3.4	46.8±5.5	NS
Sex (m:f)	13:7	9:4	4:3	NS
ASA grade 1	14	10	4	NS
ASA grade 2	6	3	3	
Hb in g% (mean±2S.E.)	11.8±0.8	11.8±0.6	12.0±0.9	NS
Albumin in g% (mean±2S.E.)	4.19±0.18	4.2±0.05	4.11±0.27	NS
Pre-op Chemotherapy	1	1	0	-
Pre-op Radiotherapy	3	2	1	NS
Bowel Preparation	18	12	6	NS
Post op. Epidural	19	12	7	NS

Here too, like the retrospective limb the morbidities were analyzed in the background of their co-morbidities/risk factors, to see if there was a causal relationship. However, the presence of anaemia, hypoalbuminaemia, other medical illnesses (as denoted by the ASA gr.), pre-op Chemotherapy or Radiation therapy did not predispose to morbidities.

Bowel preparation seems to confer no benefit in reducing morbidity, on the contrary seems to be creating problems. This observation could not be supported statistically, but seems to agree the finding that bowel preparation predisposed to morbidity.

Epidural analgesia in post-operative pain relief seems to have no statistical relationship to the incidence of ileus.

Out patient visits

Of the patients followed up in the out patient department, the most common morbidity was peristomal skin excoriation noted in two patients. However appliance accidents were common too with spillage of the effluents causing major worries amongst the ostomates. Ileostomies had a larger volume of effluents and required frequent changes and emptying. The colostomies fared badly when it came to odour. An ostomate on follow-up recently was found to have an incisional hernia at the stoma closure site.

Stoma	Skin excoriation	Others	Appliance related
Ileostomy (n=13)	2	1	4
Colostomy (n=7)	0	0	3

Skin excoriation amongst ileostomies made for the larger group with other problems not seen in the post-op follow-up at and up to 2 weeks. Appliance accidents especially spillage seems to be more frequent in the flush colostomy and less in the loop ileostomy.

Notably the appliance-related accidents became less frequent as the ostomates got familiar with its care as time passed.

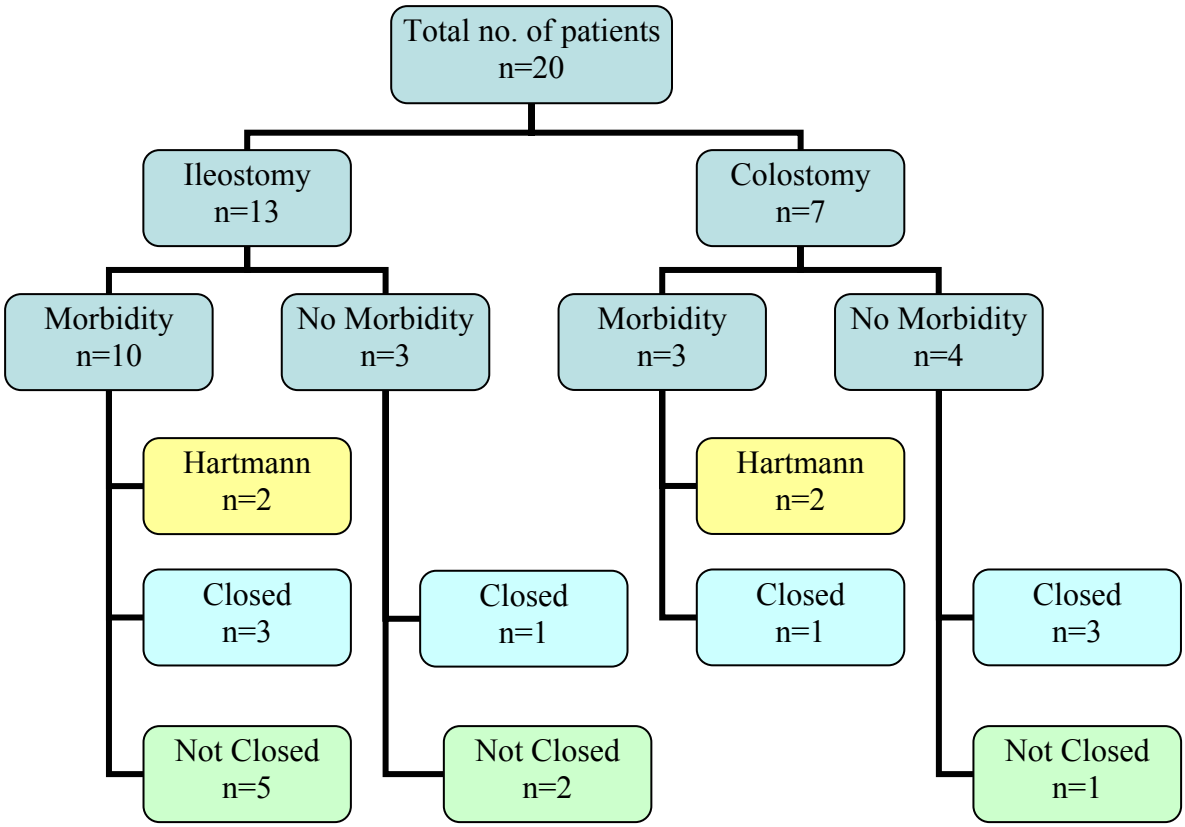
Morbidity at stoma closure in relation to co-morbidities

Of the 8 ostomates who had the closure of their stomas the only morbidity noted was ileus. Only one patient in the group had morbidity. It seemed that the other confounding factors like radiation therapy and chemotherapy, anaemia, hypoalbuminaemia, ASA grade did not contribute to morbidity.

Type of stoma and time to closure

	Study population (no. of patients) (n=8)	Ileostomy (n=4)	Colostomy (n=4)	P value
Time to Stoma Closure in days(mean ±2SE)	96.6±24.6	79.9±23.3	113.7±37.2	NS

The mean time to stoma closure was about 3 months. It was observed that ostomates with ileosomies were able to have their stomas reversed earlier than the colostomy group. Interestingly it was noted that all patients who had anastomotic leak at the time of stoma creation did not have stoma closure within the follow up period. Three out of seven patients who had anastomotic leak were converted to an end – stoma.



The above flow chart gives a summary of the study at a glance.

Of the twenty ostomates, 13 were ileostomy and 7 colostomy.

Amongst the patients with morbidity, 3 in the ileostomy and 1 in the colostomy groups got reversed, 2 in both the groups got converted to an end stoma and 5 & 1 in the respective groups were not yet closed.

In the groups without morbidity, 1 in the ilesotomy and 3 in the colostomy group were reversed and 2 & 1 in the respective wounds await closure.

Cost analysis

Interestingly a look at the costs incurred, the added morbidities and operations did not on seem to make a big difference in the costs incurred. A patient undergoing a Low Anterior Resection in the general ward incurred a cost of Rs. 50,000/- on an average with the costs increasing marginally by about Rs. 10,000/- only in case of the added morbidity.

Median Inpatient Cost vs. Stoma and Morbidity

		Morbidity		Group Total
		no	yes	
		Median	Median	Median
Stoma	colostomy	59000.00	45000.00	59000.00
	ileostomy	45000.00	57000.00	54000.00
Group Total		59000.00	54000.00	56500.00

Efficacy of decompression

The initial proposition of doing manometric studies at the site of anastomosis in the distal loop, could not be done due to, poor patient compliance.

Comparison of nutritional parameters – BMI & Hb., Alb.

All the patients dropped their BMIs by a few points but there seemed no significant difference between the types of stoma. The same pattern reflected in the other parameters considered, which were Hb. and albumin. There seems to be no disadvantage of one type of diversion over the other, although in the post-operative period these ostomates are a lesser lot than their original pre-op state.

Nutritional parameters	At primary operation	At stoma closure	P value
Haemoglobin (mean g%)	11.9 ± 2.11	12.5 ± 1.22	NS
Albumin (mean g%)	4.19 ± 0.43	4.11 ± 0.45	NS
BMI (kg/m^2)	22.9 ± 1.03	22.5±1.3	NS

QUALITY OF LIFE INDEX SCORE (Appendix IV)

A scale was designed in consideration with the WHO guidelines, to include the psycho-social, professional and stoma-care related problems. Other scales were used for reference to create a new scale. The self structured QOLIS scale was validated, before its application in the study on a population of ostomates of various indications.

Amongst our ostomates the hope of having the stoma reversed saw them in a positive state of mind with eagerness to get the stoma reversed. Their lives were plagued with adaptatonal challenges, which they coped with well.
The QOLIS was used on the ostomates when they came for their stoma reversal at 3 months.

The stoma related problems did not seem to bother the ostomates very much. However they did have a negative body image with their attractiveness and sense of hygiene significantly affected. Their interaction with their spouses and family saw no change but for their sense of “being dirty” that kept them away from intimacy.

The major fronts on which most of our ostomates found their life disabled was their social and professional life. This was directly related to their self imposed restrictions due to poor acceptance of their stoma.

The ostomates adapted themselves to their situations and found their way around problems encountered with the choice of clothes, appetite and mode of travel.

The accessibility to stoma care appliances also was not a problem, with a wide range of products to choose from amongst a wide price range. The interaction with the enterostomal therapists made a huge impact on their situation on all fronts.

From the validation process the QOLIS was revised with one of the variables being excluded for uniform conformity.

The QOLIS scores were tabulated against the revised 14 variables of three grades and scored out of 42. The scores were graded as follows

Score < 20 (44%) – poor quality of life

Score 21-34 (45-76%) – moderate quality of life

Score >35(77%) – good quality of life

Break-down of the scores amongst the stoma types

Stoma type	Personal care	Social	Psychological	Stoma- care related	Total score
Ileostomy	79%	86%	89%	93%	86.75 %
Colostomy	92%	86%	92%	85%	88.7 %

The areas of interest were problems with personal care, affect on social activities and inter-personal relationships, stoma-care related problems and the psychological impact of the whole issue on the ostomate.

The gender based difference between the variables, was negligible. The type of stoma on the whole did not seem to be a deciding factor on the quality of life. However, there were few note worthy observations;

Ileostomies appear to have more problems due to the acidic nature of its watery effluent, unlike the semi-solid, inert effluent of the colostomy. The odour of the colostomy effluent however, made it difficult for the patient. The other aspects, like appetite, diet, the choice of clothes seemed to be well adapted to, but for a few exceptions.

Social life seems to be not affected at all but their professional life has had a severe impact. The self imposed restriction in addition to the attitude at the work place to ostomates made them stay away from their work places (5/8).

The pschycological impact of the event seems to be negated by the strong support systems our ostomates had in the form of their spouses and the rest of the family. Every single ostomate did go through ‘sad’ moments, but they seem to have all recovered very well from it. They all had sensitive families which trailed with them through the difficult times, to finally see them well. The feeling of being less attractive, lack of intimacy did not look like issues common to our ostomates.

The problems faced in stoma care was seen mostly in the initial phase. Once they found the best fitting stoma appliance of their choice, care seemed to be easier. The availability of professional help at hand made care easier. The ostomates however found the choice of their stoma appliance just about affordable, as they had to experiment with different types before they settled with the most appropriate one for themselves.

On the whole our ostomates irrespective of the stoma-type have had a good quality of life, with their QOLIS scores being well above the 77% mark, at about 88%.

Discussion & Conclusions

This prospective randomized study done to look at the difference between loop ileostomies and loop colostomies seems to be a peacemaker, with neither group making a statistical impact on the variables being compared. However, there are interesting observations. Of the twenty randomized for the study, three of the cases supposed to have colostomies crossed over into the ileostomy group. This cross over was permitted as the intent to treat was primary and later on the effect was statistically evaluated. Despite the uneven distribution they seem to be comparable.

The general population seems to be in the 50s age group with more males. The hospital and post-operative stay for the ileostomy group was lesser compared to the colostomy group. This finding was supported by the finding that the ileostmy recovered faster and hence accelerated convalescence. This observation is in keeping with the observations made by Khoury et al (10) and Fasth et al (14).

The comparison based on the morbidity patterns too show ileostomies to be more morbid even though not statistically significant. This is not in keeping with the experience of the Edwards et al (8) and Rullier et al (13) studies. Another of the contradictory findings include a lager incidence of ileus in the colostomy group, unlike the study by Law et al (6).

Anastomotic leak rates though not stoma-related were found to higher with the ileostomies as was observed by the study by Gooszen et al (5) which observed that decompression of the left colon was better done by a colostomy.

The initial proposition of looking at the decompression of the distal loop, by manometric studies could no be done.

Morbidity did not appear to be influenced by the presence of co-morbidities as indicated by the ASA grades, age, gender, anaemia, hypoalbuminaemia, pre-op chemo/radiation and the use of epidural. Interestingly, bowel preparation seemed to be a predisposing factor to morbidity though not statistically supported. This is a newer outlook to the age-old controversy regarding the role of bowel preparation.

The problems faced in the out-patient clinic on follow-up show colostomies to be less problematic but for their odour. This is unlike the impression of the studies by Torkington et al (12) and Chen et al (15).

At closure, the literature is divided with Gohring et al (7,8) supporting the colostomy group and Williams et al (11) supporting the ileostomy group. Our experience due to the lack of numbers fails to find any statistical evidence to support either.

The quality of life analysis shows good quality of life for both the groups. The study by Silva et al (16) found ileostomies favourable.

Both the groups however on the nutritional front seemed to have a negative impact with both the populations having lost on the BMI, though not statistically significant.

The scope for further refinement of study design and statistical support by the required sample size could see a better set of significant results.

In summary,

1. The ileostomy appears to be the more morbid stoma (NS).
2. Ileostomies promoted earlier convalescence and hence have a shorter hospital stay (P= 0.002).
3. Colostomies appear to be more efficacious in decompressing the left colon and rectum as they were associated with lesser leak rates (NS).
4. The morbidities were independent of co-morbidities (NS).
5. Bowel preparation seemed to be associated with more morbidities (NS).
6. The stomas have a minimal effect on the nutrition and BMI (NS).
7. The quality of life, with either stoma is comparable and they have a good life (NS).

Conclusions – the prospective limb

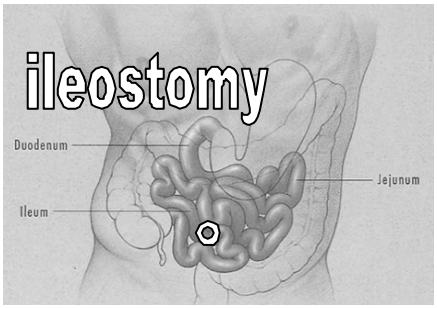
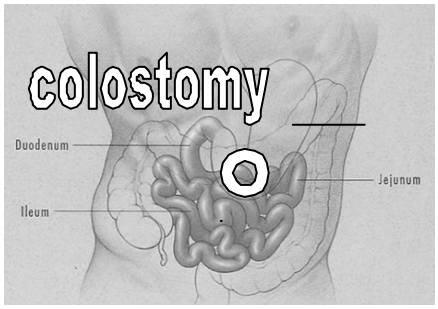
1. The incidence of morbidity amongst the ileostomies was 77% and 43% amongst the colostomies. However, this difference was not statistically significant.
2. The type of stoma did not have any effect on the nutritional status of the patients.
3. The efficacy of decompression of the distal loop, by manometric studies could not be done.
4. The quality of life in patients with loop ileostomy and loop colostomy are comparable, with both of them having a good quality of life.

APPENDIX I

PATIENT INFORMATION

The need for a STOMA in surgery for ColoRectal cancer
The surgical treatment of ColoRectal cancer involves removal of the tumour from the faecal passage and joining together of the cut ends to maintain its continuity. An opening is made in the intestine much before this site, also called STOMA, to divert stools. This diversion helps in the healing of the anastomosis.

Types of diversion/STOMA

Characteristics	**Ileostomy**	**Colostomy**
Site	Ileum-Small intestine 	Transverse Colon-Large intestine 
Nature of contents	Large volume, watery, non-offensive odour, irritates skin.	Smaller volume, semi-solid, offensive odour, not as irritative.
Problems	Intestinal obstruction Retraction Stenosis Necrosis Skin breakdown & wound infection Prolapse Stomal bleeding Parastomal hernia	Intestinal obstruction Retraction Stenosis Necrosis Skin breakdown & wound infection Prolapse Stomal bleeding Parastomal hernia

Stoma care

Both Ileostomies and Colostomies have specially designed devices for faecal collection and disposal.

The Study

This study is to compare the complications associated with intestinal stomas (Ileostomy/Colostomy) in patients who undergo surgery for Colo-Rectal Cancer with a stoma created for fecal diversion.

There is no advantage of one over the other when it comes to fecal diversion, which is the primary motive of the stoma. This study is to find out which is easier to manage and less complicated.

This study specifically looks at post-operative complications and effect of the stoma on the nutritional status, quality of life and pressures in the rectum.

Which Stoma will I get?

The choice of the stoma to be created would be decided by the study pattern and changed, if required to best suit the surgical situation. There is a 50-50 chance of either an Ileostomy or a Colostomy being created.

How long will the Stoma stay?

The Stoma would be closed around 3 months from the date of creation. This will be done only after tests are done to confirm that the anastomosis has healed.

INFORMED CONSENT

I have understood the above given information about the different types of Intestinal Stoma and their attributes.
I also understand the need for the study.
The choice I make is voluntary and will not affect the treatment that is due.
There is no obligation on me to enroll or continue in the study.

I,_____ am willing to enroll in the study knowing fully well that the execution of the same will be done in the best of my interests.

Signature of principal investigator
(Dr. Renol Koshy)

Signature of the patient

APPENDIX II

STOMA STUDY PROFORMA – FIRST ADMISSION

INCLUSION CRITERIA Age ≥ 18years Diagnosed colorectal malignancy Admitted for resectional surgery
EXCLUSION CRITERIA Patients satisfying inclusion criteria but did not have a stoma created. Also those having a change in the type of stoma.

1. CASE NUMBER:_____
2. Name :_____
3. Hospital Number:_____
4. Age (yrs):_____
5. Sex: Male – 1 / Female – 2
6. Stoma: Colostomy 1 / Ileostomy 2
7. Date of Admission: __/__/____
8. Date of Discharge: __/__/____
9. Date of Surgery: __/__/____
10. Body weight in Kg:_____
11. Height in Meters:_____
12. Pre-op Hemoglobin (g%):_____
13. Pre-op Serum Albumin (g%):_____
14. Diet: Veg. 1 / Nonveg. 2 / Mixed 3

Co morbidities

15. ASA Grade – 1 2 3 4
16. Pre-operative RT: Yes – 1 / No – 0
17. Pre-op. Chemo: Yes – 1 / No – 0
18. Bowel prep. Yes – 1 / No - 0
19. Post op Epidural Yes – 1 / No – 0

Stoma related morbidity

20. Flatus- 1 2 3 4 5 6 7_____

    Faeces-1 2 3 4 5 6 7 8 9 10 _____
21. Retraction Yes – 1 / No – 0
22. WoundInfectionYes – 1 / No – 0
23. Others Yes – 1 / No – 0

    Detail:_____
24. Re-operation: Yes – 1 / No – 0

Indication for Re-operation

25. Retraction Yes – 1 / No – 0
26. Anastomotic leak: Yes – 1 / No – 0
27. Stomal necrosis Yes – 1 / No – 0
28. Obstructed stoma Yes – 1 / No – 0
29. Others Yes – 1 / No – 0

    Detail:_____
30. Date of Initiation of normal diet:

    _____/_____/_____

OUT-PATIENT VISIT.

31. Skin excoriation Yes – 1 / No – 0
32. Retraction/Stenosis Yes – 1 / No – 0
33. Parastomal hernia Yes – 1 / No – 0
34. Prolapse Yes – 1 / No – 0
35. OthersYes – 1 / No –0_____

APPENDIX III

STOMA STUDY PROFORMA – ADMISSION FOR STOMA CLOSURE.

Adult patients with colorectal malignancy who have undergone curative surgery along with a defunctioning stoma returning after 3 months for stoma closure.

36. CASE NUMBER:_____

37. HOSPITAL NUMBER:_____

38. Date of Admission: __/__/____

39. Date of Discharge: __/__/____

40. Date of Surgery: __/__/____

41. Body weight in Kg:_____ (Ht.-_____)

42. Pre-op Hemoglobin (g%):_____

43. Pre-op Serum Albumin (g%):_____

Co morbidities

44. Pre-operative RT: Yes – 1 / No – 0

45. Pre-op. Chemo: Yes – 1 / No – 0

46. ASA Grade: 1 2 3 4

47. Others : Yes – 1/No - 0

48. Bowel prep. Yes – 1 / No - 0

49. Proph. Antibiotic Yes – 1 / No – 0

Stoma closure related morbidity

50. Ileus Yes – 1 / No – 0

51. Wound Infection Yes – 1 / No – 0

52. Others Yes – 1 / No – 0 Detail:

53. Re-operation: Yes – 1 / No – 0

Indication for Re-operation

54. Anastomotic leak: Yes – 1 / No – 0

55. Others Yes – 1 / No – 0 Detail:

APPENDIX IV

QUALITY OF LIFE PROFORMA

	Index	1	2	3
1	The stoma has affected my diet	Significantly	Moderately	Not at all
2	It has affected my appetite	Significantly	Moderately	Not at all
3	It affects my travel plans	Significantly	Moderately	Not at all
4	It affects my choice of clothes	Significantly	Moderately	Not at all
5	The care of my stoma is	Difficult	Manageable	Easy
6	It affects my social life	Significantly	Moderately	Not at all
7	The appliance is	Expensive	Affordable	Cheap
8	My appliance is	Poorly available	Not very easily available	Easily available
9	Getting help from a stoma care professional is	Difficult	Manageable	Easy
10	It has affected my – i. Marriage plans (if unmarried) ii. Childbearing plans(if married)	Significantly	Moderately	Not at all
11	It has affected my professional life	Significantly	Moderately	Not at all
12	I feel sad	Always	Sometimes	Never
13	I feel less attractive	Significantly	Moderately	Not at all
14	It has affected my i. Intimacy with my spouse (if married) ii. Interaction with the opposite sex (if unmarried)	Significantly	Moderately	Not at all
15	It has affected my position in the family	Significantly	Moderately	Not at all

TOTAL SCORE = _____/ 45

Pressure study details:

Rectal pressures:_____

Anal pressures :_____

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